**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF TEXAS**
**MARSHALL DIVISION**

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| FOUNDATION MEDICINE, INC.,<br><br>Plaintiff,<br><br>v.<br><br>GUARDANT HEALTH, INC.,<br><br>Defendant. | Civil Action No. 2:16-cv-00523<br><br>**JURY TRIAL DEMANDED** |

## COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Foundation Medicine, Inc. ("Foundation Medicine"), by its attorneys, for its Complaint For Patent Infringement, alleges as follows:

## NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 9,340,830 ("the '830 patent") arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq*. The action arises out of the infringement of one or more claims of the '830 patent as a result of the use, manufacture, offer for sale, sale, and/or importation by defendant Guardant Health, Inc. ("Guardant") of its Guardant360 genomic cancer testing.

## PARTIES

2. Plaintiff Foundation Medicine is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 150 Second Street, Cambridge, MA 02141.

3. Defendant Guardant is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 505 Penobscot Dr., Redwood City, CA 94063. The cause of action against Guardant in this Complaint arose from or is connected with purposeful acts committed by Guardant in Texas because, upon information and belief, within the State of Texas and this District, Guardant (a) uses, sells, offers to sell and/or imports its infringing products and services, (b) induces others to sell or offer to sell the infringing products and services, (c) or transacts other business in Texas. Accordingly, pursuant to Federal Civil Rule of 4, sections 17.044(a)-(b) and 17.045(a) of the Texas Civil Practice & Remedies Code, and Texas Business Organizations Code § 5.251-2, Guardant may be served with process by serving the Texas Secretary of State, James E. Rudder Building, Attn: Service of Process, 1019 Brazos Street, Room 105, Austin, Texas 78701, as its substituted agent for service of process because (1) the Texas Secretary of State is the agent for service on Guardant, (2) Guardant engaged and engages in business in Texas, (3) Guardant does not maintain a regular place of business in Texas, (4) Guardant does not have a designated agent for service of process in Texas, and (5) this lawsuit arises from Guardant's business in Texas. Guardant's "home office" is located at 505 Penobscot Dr., Redwood City, CA 94063. Therefore, the Texas Secretary of State shall mail a copy of the summons and this Complaint to Guardant's home office at: Guardant Health, Inc., Attn: Helmy Eltoukhy Ph.D., CEO, 505 Penobscot Dr., Redwood City, CA 94063.

## JURISDICTION AND VENUE

4. This action arises under the patent laws of the United States, Title 35 of the United States Code. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

5. Guardant is subject to personal jurisdiction in this District because, upon information and belief, Guardant has purposely availed itself of the rights and benefits of the laws of Texas, has had persistent, systematic and continuous contacts with Texas, and has purposefully directed activities at residents of this forum. Among other things, Guardant is in the business of providing genomic cancer testing. Upon information and belief, Guardant markets and sells such testing throughout the United States, including in Texas and specifically in this District.

6. Upon information and belief, Guardant regularly and continuously transacts business within Texas, including availing itself of the privilege of conducting business in Texas. Guardant maintains a Texas Taxpayer Number with the Texas Office of the Comptroller.

7. Upon information and belief, Guardant offers Guardant360 tests for sale in the United States, including in Texas and specifically in this District. Exhibit 1 (Guardant Health, Guardant360 (webpage with "Request a Guardant360 kit" link, which allows users to make a request originating from all 50 states)); Exhibit 2 (landing page for the "Request a Guardant360 kit" showing Texas option).

8. Guardant also maintains a website for Guardant360, http://www.guardant360.com, which promotes Guardant360 for sale throughout the United States, including in Texas. Upon information and belief, Guardant360 testing is available for purchase and use by customers in Texas and specifically in this District.

9. Upon information and belief, Guardant has offered and sold its Guardant360 test to customers in Texas, including in this District. In particular, upon information and belief, Guardant has sold its Guardant360 test to at least the following cancer centers in this District: Cancer Center Associates at Rena Tarbet Cancer Center in McKinney, Texas; Texas Oncology –

McKinney South, in McKinney, Texas; Plano Cancer Institute in Plano, Texas; Texas Oncology – Plano East, in Plano, Texas; and Texas Oncology – Tyler, in Tyler Texas. In addition, upon information and belief, Guardant has sold its Guardant360 test to the following cancer centers in Texas: Texas Oncology – Amarillo, Amarillo, Texas; The Center for Blood and Cancer Disorders – Ft. Worth, Texas; Arlington Cancer Center, Arlington, Texas. Upon information and belief, Guardant also has marketed its Guardant360 test to the following cancer centers in this District: Texas Oncology – McKinney, in McKinney, Texas; Medical Center of Plano, in Plano, Texas; Texas Oncology – Plano Presbyterian, in Plano, Texas; Texas Oncology – Plano West, in Plano, Texas; Blood & Cancer Center of East Texas, in Tyler, Texas; and Tyler Hematology Oncology.

10. Upon information and belief, Guardant has performed the Guardant360 test on samples drawn from patients in Texas, including at the MD Anderson Cancer Center in Houston, Texas. *See* Exhibit 3 (Lanman et al., *Analytical and Clinical Validation of a Digital Sequencing Panel for Quantitative, Highly Accurate Evaluation of Cell-Free Circulating Tumor DNA*, PLoS ONE 10(10); e0140712 (Oct. 16, 2015)).

11. Upon information and belief, Guardant has committed and continues to commit acts of patent infringement in Texas and specifically in this District, and as a result has harmed and continues to harm Foundation Medicine.

## BACKGROUND

### A. FOUNDATION MEDICINE AND THE INVENTION

12. Foundation Medicine is a molecular information company focused on changing the way in which patients with cancer are evaluated and treated by, among other things, pursuing an information-based approach to making clinical treatment decisions based on comprehensive genomic profiling. The company's genomic analysis products (FoundationOne®,

FoundationOne® Heme, and FoundationACT™) are designed to provide genomic profiles generated from tumor tissue, blood, or other sample inputs, utilizing next-generation sequencing technology.

13. On May 17, 2016, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 9,340,830, entitled "Optimization of Multigene Analysis of Tumor Samples", which is solely assigned to Foundation Medicine. The claims of the '830 patent are valid and enforceable. A true and correct copy of the '830 patent is attached as Exhibit 4.

14. The '830 patent describes and claims novel methods of analyzing a patient sample to detect various types of mutations that may be relevant to the patient's cancer.

15. Prior to Foundation Medicine's groundbreaking invention, there was a longstanding, unmet need for more sensitive, reliable, and efficient methods to detect complex, low frequency somatic mutations associated with cancer. Conventional, state-of-the-art cancer diagnostic screening methods suffered from various shortcomings, including their inability to detect certain types of somatic mutations and the need to obtain relatively large quantities of tissue samples for multiple rounds of testing.

16. The '830 patent's invention solves these problems by using tailored bait sets combined with next-generation sequencing to accomplish more reliable detection of multiple classes of genomic alterations in tumor samples in one test. The invention is therefore a significant advance over prior conventional genomic diagnostic methods and results in a more complete, more sensitive, and more efficient cancer genomic diagnostic assay. The claimed methods permit doctors to develop better targeted, personalized therapies for cancer patients, with the goals of identifying and providing more effective drugs for the individual patient,

improving outcomes, and reducing the harsh side effects typically associated with less targeted, systemic cancer treatments.

### B. GUARDANT'S INFRINGING GENOMIC TEST

17. Guardant's genomic diagnostic product, Guardant360, practices one or more of the inventions claimed in the '830 patent.

18. Upon information and belief, on February 12, 2014, Guardant began offering Guardant360 for sale to healthcare providers across the U.S. Exhibit 5 (Guardant Health, Press Release, *Guardant Health Releases Breakthrough Blood Test to Improve Cancer Treatment* (Feb. 12, 2014) (announcing commercial availability, and noting that "[t]he test is now available to select cancer centers across the United States")).

19. Upon information and belief, Guardant provides a sample collection kit to healthcare providers to obtain a sample from a patient. *See* Exhibit 6 (National Institutes of Health, National Center for Biotechnology Information, Genetic Testing Registry, Tests: Guardant360, http://www.ncbi.nlm.nih.gov/gtr/tests/527948/overview). Customers ship patient samples back to Guardant, and Guardant conducts testing on those samples in its laboratory. Guardant delivers the results via an online portal accessible by customers throughout the United States, including in Texas. *See* Exhibit 1, Guardant Health, Guardant360: How It Works (http://www.guardanthealth.com/guardant360/#how-it-works).

20. Guardant360 is a genomic analysis test intended to evaluate cell-free circulating tumor DNA performed with next-generation sequencing methods. The Guardant360 test comprises a method of analyzing a tumor sample for somatic mutations. *See* Exhibit 3 (Lanman et al., *Analytical and Clinical Validation of a Digital Sequencing Panel for Quantitative, Highly Accurate Evaluation of Cell-Free Circulating Tumor DNA*, PLoS ONE 10(10); e0140712 (Oct. 16, 2015).

21. Upon information and belief, the Guardant360 test generates a library of DNA molecules from a patient sample that includes sequences from tumor cells. *See id.* at 3 ("Digital sequencing . . . employs pre-sequencing preparation of a digital library of individually tagged cfDNA molecules combined with post-sequencing bioinformatics reconstruction to eliminate nearly all false positives."); *id.* ("Guardant360 is an NGS panel of 54 clinically actionable genes (S1 Table) utilizing digital sequencing of cell-free circulating tumor DNA isolated from a simple, non-invasive blood draw.").

22. Upon information and belief, the Guardant360 test uses multiple custom bait sets to hybridize and thereby capture target DNA that includes tumor-related somatic mutations from the library, enriching for certain target genes. *See id.* at 17 (noting that Guardant360 targets exons that include tumor genomic alterations using "capture probes"); *see also id.* at 18 (noting that the libraries are "subsequently enriched for target genes using biotinylated custom baits of RNA probes"); *id.* at Supplementary Figure 2 (showing that four types of tumor genomic alterations are detected (single nucleotide variants ("SNVs"), copy number variants ("CNVs"), fusions, and insert/deletions ("indels"))); *see also id.* at 3 (noting that the Guardant360 test detects "single nucleotide variants in all 54 genes and copy number amplifications in EGFR, ERBB2 (codes for HER2) and MET.").

23. Upon information and belief, the bait-captured target DNA molecules are then sequenced using a next-generation sequencing method to generate reads for subgenomic intervals that include tumor-related somatic mutations. *See id.* at 3 ("Guardant360 is an NGS [next-generation sequencing] panel of 54 clinically actionable genes."); *id.* at 5 (indicating in "Workflow for the Guardant360 cell-free circulating DNA NGS genomic profile" that digital

sequencing uses "optimized NGS to determine the genomic sequences); *id*. at 17 (describing test as "cfDNA NGS panel").

24. Upon information and belief, Guardant analyzes the reads by aligning them to reference sequences by an alignment method. *See id.* at 19 ("Software utilized includes CASAVA (version 1.8.4), the open source BWA-MEM aligner, and a custom read pile-up process that utilizes information encoded by digital-sequencing oligonucleotides to reconstruct the set of unique cfDNA molecules. First, 150bp paired-end reads are aligned to the reference genome. Trim_galore, a wrapper script for cutadapt, is used to remove lower quality 3' adapter sequences, and custom scripts are used to remove unaligned sequences and trim low quality tails and adapter contaminations.").

25. Upon information and belief, the Guardant360 test then assigns nucleotide values from the aligned read for preselected nucleotide positions and thereby analyzes the tumor sample for a somatic mutation. *See id.* at 19 (indicating that "Custom scripts are then used to (a) remove spurious variants ('noise') created by sequencing errors, (b) identify all germline single nucleotide polymorphisms (SNPs) and somatic single nucleotide variants (SNVs), and (c) call somatic SNVs"); *see also id.* at 5, Figure 1 (indicating in "Workflow for the Guardant360 cell-free circulating DNA NGS genomic profile" that the test performs "complete sequencing" and "reconstruct[s] the progenitor cfDNA fragment sequences" from the digital library).

26. Upon information and belief, Guardant chooses the custom bait sets used by the Guardant360 test in order to capture target DNA molecules that include tumor-related somatic mutations. *See id.* at 18 ("These digital sequence libraries are amplified and then subsequently enriched for target genes using biotinylated custom baits of RNA probes."). Upon information and belief, the Guardant360 test uses multiple custom bait sets to target at least the following

types of somatic mutations: SNVs (*see id.* at 3 & Supplementary Figure 2); CNVs (*see id.* at 3, 5 & Supplementary Figure 2); gene fusions (*see id.* at 5 & Supplementary Figure 2); and indels, including gene truncations (*see id.* at 5 & Supplementary Figure 2).

27. Upon information and belief, each of the custom bait sets used by the Guardant360 test has a unique preselected efficiency for selection of its target.

28. Guardant's manufacture, use, offer for sale, sale, and/or importation of Guardant360 infringes at least one claim of the '830 patent.

### C. GUARDANT'S KNOWLEDGE OF THE PATENT-IN-SUIT

29. Upon information and belief, Guardant had knowledge of the '830 patent application prior to the filing of this lawsuit.

30. Guardant cited the '830 patent application in its patent application numbers 14861989 (information disclosure statement ("IDS") dated December 17, 2015), 14855301 (IDS dated October 13, 2015), 13969260 (IDS dated June 26, 2015), and 14712754 (IDS dated May 28, 2015).

31. Further, upon information and belief, Guardant, as a competitor of Foundation Medicine, closely monitored Foundation Medicine's filing of patent applications and the status of prosecution of those patent applications.

32. Upon information and belief, Guardant knows or should know that its Guardant360 product infringes and will infringe the '830 patent.

### COUNT I -- INFRINGEMENT OF THE '830 PATENT UNDER 35 U.S.C. § 271(a)

33. Foundation Medicine incorporates each of the preceding paragraphs 1-31 as if fully set forth herein.

34. Guardant's commercial manufacture, use, offer for sale, sale, and/or importation of its Guardant360 product does and will constitute an act of infringement of one or more claims of the '830 patent under 35 U.S.C. § 271(a).

35. Guardant has committed and will commit these acts of infringement without license or authorization.

36. Upon information and belief, Guardant has knowledge of the '830 patent.

37. Upon information and belief, Guardant knows or should know that its manufacture, use, sale, offer for sale, and/or importation of its Guardant360 product does and will constitute an unjustifiably high risk of infringement of the '830 patent.

38. Upon information and belief, despite an objectively high likelihood that its actions do and will constitute infringement of a valid patent, Guardant continues to manufacture, use, sell, offer to sell, and/or import Guardant360. Thus, infringement by Guardant is willful.

## PRAYER FOR RELIEF

WHEREFORE, Foundation Medicine requests the following relief:

(a) Judgment that Guardant's manufacture, use, offer for sale, sale, and/or importation of its Guardant360 product infringes one or more claims of the '830 patent;

(b) Judgment awarding Foundation Medicine damages resulting from such infringement, increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

(c) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(d) An award of Foundation Medicine's costs and expenses in this action; and

(e) Such further and other relief as this Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff demands a jury trial as to all matters triable of right by a jury.

Respectfully submitted,

Dated: May 17, 2016

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